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IN THE UNITED STATES DISTRICT COURT

FOR THE NORTHERN DISTRICT OF CALIFORNIA

SAN JOSE DIVISION

HOLOGIC, INC., CYTYC CORP. and HOLOGIC L.P.,

Plaintiffs,

v.

SENORX, INC.,

Defendant.

No. C-08-00133 RMW

ORDER REGARDING SUPPLEMENTAL CLAIM CONSTRUCTION AND SUMMARY JUDGMENT

[Re Docket No. 284, 448, 449, 450]

On February 18, 2009, the court issued a claim construction order, construing disputed terms and language in the claims of United States Patent Nos. 5,913,813 ("'813 Patent"), 6,413,204 ("'204 Patent"), and 6,482,142 ("'142 Patent"). Plaintiffs Hologic, Inc., Cytyc Corp., and Hologic, L.P. (collectively "Hologic") and defendant SenoRx, Inc. ("SenoRx") move for supplemental claim construction. The court construes the disputed terms and language as set forth below.

I. BACKGROUND

The parties develop products for use in breast brachytherapy. Brachytherapy is a form of radiation therapy whereby a radioactive source is placed inside or near an area requiring treatment. For breast brachytherapy, breast tumors are removed via a lumpectomy procedure and a device for

delivering radiation is placed in the tumor cavity. The goal of such treatment is to more efficiently deliver radiation to any remaining cancerous tissue while minimizing damage to healthy tissue.

SenoRx markets a balloon brachytherapy device known as the Contura Multi-Lumen Balloon ("Contura") which allegedly infringes Hologic's patents. The Contura has five lumens, one straight central lumen and four surrounding curved lumens arranged at ninety degree increments around the central lumen. Within each lumen, radioactive sources can be placed at different positions (called "dwell positions") along the length of the lumen within the balloon. Physicians develop dose plans during treatment to deliver a particular prescribed radiation dose to the target tissue. Because the Contura has multiple dwell positions and multiple lumens in which sources can be placed as part of the dose plan, the parties divide the plans into three relevant categories: (1) plans that utilize multiple dwell positions including the central lumen/central dwell position ("multi-dwell/central" category), (2) those that utilize multiple dwell positions but do not utilize the central lumen/central dwell position ("multi-dwell/no central" category), and (3) those that use the central lumen/central dwell position only ("single-dwell/central" category).

II. ANALYSIS

A. "Minimum Prescribed Absorbed Dose" Limitation in Claim 2 of the'204 Patent

In its motion for summary judgment of non-infringement, SenoRx contended that the multi-dwell position plans do not meet the "minimum prescribed absorbed dose" limitation to claim 2 of the '204 Patent. SenoRx's argument is that "minimum prescribed absorbed dose" means the total delivered dose to the target tissue. As a result, for any particular dwell position and source in a multi-dwell plan, the dose of radiation delivered to the tissue will be less than the minimum prescribed dose because the dose delivered by sources at other dwell positions contribute to the total dose. Thus, the multi-dwell position plans do not meet this limitation, and the court should grant summary judgment of non-infringement for these plans.

Hologic did not respond to this argument until its reply in support of its own motion for summary judgment and claimed that SenoRx had failed to previously disclose this non-infringement position. Hologic requested further briefing on this issue. The court granted leave for the parties to file supplemental briefing on this issue and withheld ruling on SenoRx's motion for summary

judgment on claim 2 because the meaning of the "minimum prescribed absorbed dose" limitation was potentially dispositive.

Having reviewed the parties' supplemental briefs, the court finds that "minimum prescribed absorbed dose" means the total delivered dose to the target tissue. Three reasons support this construction. First, failing to interpret this language to mean the total dose would read "prescribed" out of the claim. The plain meaning of a "prescribed" dose is the dose prescribed by a physician to be delivered to a patient during a course of radiation treatment. Hologic has provided no evidence that physicians ever prescribe less than the total dose to be delivered to the target tissue. Because a "claim construction that gives meaning to all the terms of the claim is preferred over one that does not do so," *Merck & Co., Inc. v. Teva Pharmaceuticals USA, Inc.*, 395 F.3d 1364, 1372 (Fed. Cir. 2005), the court finds that "minimum prescribed absorbed dose" refers to the total delivered dose.

Second, this construction is supported by the specification. Claims are read in view of the specification, which is the "single best guide to the meaning of the disputed term." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1315 (Fed. Cir. 2005). In the "Summary of the Invention" section of the specification, the patent states: "[t]he predetermined dose range is defined as being between a minimum prescribed absorbed dose for delivering therapeutic effects to tissue that may include cancer cells, and a maximum prescribed absorbed dose above which healthy tissue necrosis may result." '204 Patent 2:52-55 (emphasis added). Since the purpose of the invention is to deliver radiation to target tissue with a desired intensity without overexposing un-targeted tissue and causing healthy tissue necrosis (*id.* at 2:27-32), "maximum prescribed absorbed dose" must refer to the maximum total delivered dose to target tissue. After all, the objective is to keep the total delivered dose low enough such that it does not cause healthy tissue necrosis. Given that "maximum prescribed absorbed dose" refers to the maximum total delivered dose, one of ordinary skill in the art would logically conclude that "minimum prescribed absorbed dose" refers to the minimum total delivered dose.

In addition, the specification also states: "After a prescribed absorbed dose has been delivered to tissue surrounding the apparatus, the apparatus is removed." *Id.* at 3:9-11. As pointed

out by SenoRx, no balloon brachytherapy device is removed prior to the complete delivery of treatment. Therefore, this language in the specification also demonstrates that a "prescribed absorbed dose" must refer to the total delivered dose.

Third, this construction is supported by the language in dependent claim 5: "wherein the minimum prescribed absorbed dose is 40 Gray." '204 Patent 8:47-48. The parties agree that the total, cumulative dose delivered to tissue during treatment is 34 Gray, and Hologic concedes that in claim 5, the minimum prescribed absorbed dose of 40 Gray would likely be the total, cumulative dose delivered to tissue during a course of treatment. Plaintiffs' Supplemental Brief p. 3. The Federal Circuit has made it clear that claim language in other claims is useful in construing a disputed claim term:

> Other claims of the patent in question, both asserted and unasserted, can also be valuable sources of enlightenment as to the meaning of a claim term. Because claim terms are normally used consistently throughout the patent, the usage of a term in one claim can often illuminate the meaning of the same term in other claims.

Phillips, 415 F.3d at 1314. Therefore, the fact that "minimum prescribed absorbed dose" is understood to mean the total delivered dose in claim 5 is strong evidence that "minimum prescribed absorbed dose" also means total delivered dose when used in claim 2.

For the foregoing reasons, the court construes "minimum prescribed absorbed dose" to mean the total delivered dose to the target tissue. As a result, the court also grants summary judgment of non-infringement of claim 4 of the '204 Patent with respect to multi-dwell dose plans using the Contura.

For use of the Contura to infringe claim 4 of the '204 Patent, it must meet both the "minimum prescribed absorbed dose" limitation of claim 2 as well as the "predetermined spacing" limitation of claim 3. The court construed the "predetermined spacing" limitation to require fixed spacing, predetermined by one skilled in the art before administering radiation, between the wall or edge of the inner spatial volume and the expandable surface element, which for each point on the wall or edge of the inner spatial volume, the distance to the closest point on the expandable surface element is the same (i.e. the inner spatial volume and the expandable surface element are concentric and the same shape). Claim Construction Order pp. 4-5. To meet this limitation, the inner spatial volume must be a radionuclide which is placed in the center position of the Contura's central lumen. When

the radiation source is placed in any other position, the spacing between the inner spatial volume and the balloon (the Contura's expandable surface element) is not the same for every point on the inner spatial volume.

To meet the "minimum prescribed absorbed dose" limitation of claim 2, the inner and outer spatial volumes must be configured to provide the minimum total delivered dose for delivering therapeutic effects to the target tissue. As SenoRx points out in its supplemental brief, for any multi-dwell dose plan, the dose delivered from any one dwell position is less than the total delivered dose because sources at other dwell positions contribute to the total delivered dose. Since the central dwell position is the only position that meets the "predetermined spacing" limitation, and the dose delivered from the central dwell position in a multi-dwell plan is necessarily less than the "minimum prescribed absorbed dose," use of the Contura with multi-dwell plans does not infringe claim 4 of the '204 Patent.

B. "Three-Dimensional Isodose Profile" Limitation in Claim 1 of the '204 Patent

In its claim construction order, the court construed the "three-dimensional isodose profile" language in claim 1 of the '204 Patent as not being limited to the final, cumulative absorbed dose. Claim Construction Order pp. 6-7. SenoRx seeks further clarification of the court's claim construction of this term and contends that the "three-dimensional isodose profile" refers to the profile at the end of a fraction of treatment, not the profile from each dwell position. Because the court has granted summary judgment of non-infringement of claim 4 of the '204 Patent for use of the Contura with multi-dwell plans, there appears to be no need to further construe this claim language. Further, the court is not certain that it understands what SenoRx means by "any one fraction of treatment."

C. "Causing" Language in Claim 8 of the '142 Patent

In its October 30, 2009 order, the court denied the motion for summary judgment of invalidity of claim 8 of the '142 Patent due to anticipation by the Ashpole reference.[1] Claim 8 of the '142 Patent contains the following limitation: "wherein the expandable outer surface is sufficiently

[1] The Ashpole reference is described in detail in the court's October 30, 2009 summary judgment order pp. 7-9.

rigid to deform the target tissue into the shape of the expandable outer surface, causing the predetermined asymmetric isodose curves to penetrate the target tissue to a prescribed depth." '142 Patent 10:13-17. SenoRx argued that Ashpole inherently disclosed this claim limitation because the balloon in Ashpole is sufficiently rigid to deform the target tissue. This court nonetheless denied summary judgment because the limitation requires both sufficient rigidity to deform and that such deformation would cause penetration to a prescribed depth. Not recognizing the latter requirement would read the language "causing the predetermined asymmetric isodose curves to penetrate the target tissue to a prescribed depth" out of the claim.

Unfortunately, the language in the court's earlier order, which stated that the specified rigidity must be used towards the claim's stated purpose, may have caused some confusion to the parties regarding the court's meaning. To clarify, the court does not hold that the rigidity in the balloon in Ashpole must have been recognized and used for the same purpose as the patented invention in order to anticipate the invention. The Federal Circuit has clearly rejected the contention that inherent anticipation requires recognition in the prior art. *Schering Corp. v. Geneva Pharmaceuticals, Inc.*, 339 F.3d 1373, 1377 (Fed. Cir. 2003); *see also Titanium Metals Corp. of America v. Banner*, 778 F.2d 775, 782 (Fed. Cir. 1985) ("Congress has not seen fit to permit the patenting of an old alloy, known to others through a printed publication, by one who has discovered its corrosion resistance or other useful properties"). This is a natural result of the patent law principle, "that which would literally infringe if later in time anticipates if earlier." *Schering*, at 1379 (quoting *Bristol-Myers Squibb Co. v. Ben Venue Labs., Inc.*, 246 F.3d 1368, 1378 (Fed. Cir. 2001)). Regardless of whether a person having ordinary skill in the art would have recognized that the balloon in Ashpole had sufficiently rigidity to deform target tissue, Ashpole anticipates claim 8 of the '142 Patent if it meets each and every claim limitation.

Now both parties move for supplemental claim construction of the term "causing" in claim 8 of the '142 Patent. Hologic contends that "causing" should be construed to mean "with the purpose of allowing," while SenoRx contends that "causing" should be construed as "which would allow." As discussed above, anticipation does not require recognition of purpose in the prior art. Therefore, the court declines to adopt Hologic's proposed construction. However, SenoRx's proposed

construction could be read to suggest a distinction between the phrase "which would allow" (passive language - allowing an event to occur) and the word "causing" (active language - producing an event or result). Because the court finds that the plain meaning of "causing" would be easily understood by the jury and would be more clear than construing the term as "which would allow," the court also declines to adopt SenoRx's proposed construction.

III. ORDER

For the foregoing reasons, the court:

1. grants the motion for permission to file supplemental claim construction briefs;

2. construes "minimum prescribed absorbed dose" in claim 2 of the '204 Patent to mean "minimum total delivered dose to the target tissue";

3. grants summary judgment of non-infringement of claim 4 of the '204 Patent with respect to use of the Contura for multi-dwell plans; and

4. finds that the "causing" language in claim 8 of the '142 Patent does not require further construction.

DATED: 11/24/09

Ronald M. Whyte

RONALD M. WHYTE
United States District Judge

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